DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 02N–0035]

Mylan Pharmaceuticals et al.; Withdrawal of Approval of 34 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 34 abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective [*insert date 30 days after date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
61–530	Penicillin V Potassium Tablets USP, 250 milligrams (mg) and 500 mg.	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310 Morgantown, WV 26504–4310.
61–829	Ampicillin for Oral Suspension USP, 125 mg/5 milliliters (mL) and 250mg/5 mL.	Do.
62–067	Amoxicillin Capsules USP, 250 mg and 500 mg	Do.
62–104	Neomycyin Sulfate with Hydrocortisone Ointment USP, 0.35% and 1%.	Clay-Park Laboratories, Inc., 1700 Bathgate Ave., Bronx, NY 10457.
62–280	Nystatin and Triamcinolone Acetonide Ointment USP	Do.
62–372	Mezlin (sterile mezlocillin sodium)	Bayer Corp. Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516.
62–697	Mezlin (sterile mezlocillin sodium)	Do.

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ANDA No.	Drug	Applicant
71–099	Bromatapp ER (brompheniramine maleate/phenylpropanolamine hydrochloride (HCl)) Extended-Release Tablets, 12 mg/75 mg.	Copley Pharmaceuticals, Inc., 25 John Rd. Canton, MA 02021.
71–551	Flurazepam HCl Capsules USP, 30 mg	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
71–927	Flurazepam HCl Capsules USP, 15 mg	Do.
72–027	Fentanyl Citrate and Droperidol Injection	AstraZeneca LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355.
72–070	Nalbuphine HCl Injection USP, 10 mg/mL	Do.
72–073	Nalbuphine HCl Injection USP, 20 mg/mL	Do.
72–921	Prazosin HCl Capsules USP, 2 mg	Purepac Pharmaceutical Co.
72–991	Prazosin HCl Capsules USP, 1 mg	Do.
72–992	Prazosin HCl Capsules USP, 5 mg	Do.
73–690	Calcitonin-Salmon Injection, 200 international units/mL	AstraZeneca LP.
74–579	Betamethasone Dipropionate Cream USP, 0.05% (base)	Clay-Park Laboratories, Inc.
75–263	Midazolam HCl Injection, 5 mg (base)/mL	AstraZeneca LP.
75–348	Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL.	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543–4500.
75–355	Labetalol HCl Injection USP, 5 mg/mL	Do.
75–620	Midazolam HCl Injection, 1 mg (base)/mL and 5 mg (base)/mL.	Do.
75–641	Midazolam HCl Injection, 5 mg (base)/mL	Do.
75–642	Bisoprolol Fumarate and Hydrochlorothiazide Tablets	Do.
75–707	Famotidine Injection, 10 mg/mL	Do.
75–708	Famotidine Injection, 10 mg/mL (preservative free)	Do.
83–115	Niacin Tablets USP, 500 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
84–968	Nitrofurazone Ointment USP, 0.2%	Clay-Park Laboratories, Inc.
85–130	Nitrofurazone Topical Solution USP, 0.2%	Do.
86–424	Triple Sulfa Vaginal Cream	Altana Inc., 60 Baylis Rd., Melville, NY 11747.
86–810	Fluocinolone Acetonide Cream USP, 0.01%	Clay-Park Laboratories, Inc.
86–811	Fluocinolone Acetonide Cream USP, 0.025%	Do.
89–784	Meperidine HCl Injection USP, 50 mg/mL	AstraZeneca LP.
89–788	Meperidine HCl Injection USP, 1,000 mg/mL	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research

(21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective [*insert date 30 days after date of publication in the* **Federal Register**].

Dated: 2/12/02

February 12, 2002.

Steven K. Galson,
Deputy Director,
Center for Drug Evaluation and Research.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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